
From: Charles Boyd[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30586A8D51E34852A9CD931EE5ECEB7C-CHARLES BOYD]
Sent: Wed 3/17/2021 1:52:21 PM (UTC)
To: Martha M. Rumore[mrumore@frierlevitt.com]; Abbie Divilio[AbbieD@Safechain.com]
Subject: RE: e-Pharm/alert: Notice: Illegitimate Biktarvy(R)/Descovy(R) Sourced from Unauthorized Gilead Distributors
Attachment: Gilead Letter.pdf

Hi Martha,

Thank you for putting this initial response letter together so quickly. I doctored it up a little more and have attached it for your records. Thanks!

Charlie



Charlie Boyd | Founder & CEO
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 | Cell: 301.875.1581
www.SafeChain.com | [LinkedIn](#)

From: Martha M. Rumore <mrumore@frierlevitt.com>
Sent: Tuesday, March 16, 2021 4:01 PM
To: Charles Boyd <CharlesB@Safechain.com>; Abbie Divilio <AbbieD@Safechain.com>
Subject: RE: e-Pharm/alert: Notice: Illegitimate Biktarvy(R)/Descovy(R) Sourced from Unauthorized Gilead Distributors

Hi Charlie:

I will tend to this by this evening. Letter to go out tomorrow morning.
We never heard back from Gilead regarding several quality reports, nor their findings, and now they issue this....

Best,

Martha

Martha M. Rumore, PharmD, MS, JD, LLM
Senior Counsel

FRIER LEVITT
ATTORNEYS AT LAW

GOVERNMENT
EXHIBIT

245

1:24-cr-20255-WPD

GX 245.001

DOJ-PPM-0000119910

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From: Charles Boyd <CharlesB@Safechain.com>
Sent: Tuesday, March 16, 2021 3:38 PM
To: Abbie Divilio <AbbieD@Safechain.com>; Martha M. Rumore <mrumore@frierlevitt.com>
Subject: FW: e-Pharm/alert: Notice: Illegitimate Biktarvy(R)/Descovy(R) Sourced from Unauthorized Gilead Distributors
Importance: High

[EXTERNAL SENDER: This message came from an EXTERNAL address. DO NOT click on links or attachments unless you know the sender and the content is safe.]
Please see below. We have pharmacies asking for a formal response to this on company letterhead.
This response should include:

- Safe Chain was made aware of this situation and reported this to Gilead immediately.
- Safe Chain no longer works with Gentek as pharmaceutical supplier.
- Safe Chain is only a wholesaler selling finished goods, not a repacker. We never open or tamper with any packaging.
- Gilead only has 17 AD's and there is nothing wrong or illegal with buying and selling these products from other licensed wholesalers.
- All products must have proper T3 documentation tracing the products back to Gilead and their AD

Am I missing anything else? I need to get this done ASAP and out to customers before we have a major issue.



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From: Adam Brosius <adam@pharmasales.com>
Sent: Tuesday, March 16, 2021 3:03 PM
To: Charles Boyd <CharlesB@Safechain.com>; Garrett Mellott <garrett@pharmasales.com>; Pat Boyd <PatB@Safechain.com>
Subject: Fwd: e-Pharm/alert: Notice: Illegitimate Biktarvy(R)/Descovy(R) Sourced from Unauthorized Gilead Distributors

----- Forwarded message -----

From: Emin Emin <emin@pharmasales.com>
Date: Tue, Mar 16, 2021 at 1:56 PM
Subject: Fwd: e-Pharm/alert: Notice: Illegitimate Biktarvy®/Descovy® Sourced from Unauthorized Gilead Distributors
To: Adam Pharam Sales Brosius <adam@pharmasales.com>, Garrett Mellott <garrett@pharmasales.com>

Emin Noorijanian
World Wide Pharma Sales
Cell: 818-395-1706
[Email: Emin@pharmasales.com](mailto:Emin@pharmasales.com)

Begin forwarded message:

From: Global <globalexpressrx@gmail.com>
Subject: Fwd: e-Pharm/alert: Notice: Illegitimate Biktarvy®/Descovy® Sourced from Unauthorized Gilead Distributors
Date: March 16, 2021 at 1:54:32 PM EST
To: "Emin N." <Emin@pharmasales.com>

Begin forwarded message:

From: Tuan La <globalexpressrx@gmail.com>
Date: March 16, 2021 at 11:42:11 AM PDT
To: Kevin Tran <TLCxpress@yahoo.com>
Subject: Fwd: e-Pharm/alert: Notice: Illegitimate Biktarvy®/Descovy® Sourced from Unauthorized Gilead Distributors

----- Forwarded message -----

From: e-Pharm/alert <epharmalert@alertmarketingmail.com>
Date: Tue, Mar 16, 2021 at 11:29 AM
Subject: e-Pharm/alert: Notice: Illegitimate Biktarvy®/Descovy® Sourced from Unauthorized Gilead Distributors
To: <globalexpressrx@gmail.com>

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March 16, 2021

Dear Pharmacist:

Gilead Sciences, Inc. is writing to inform you that three pharmacies in the United States have reported four separate instances in which patients have returned bottles of Gilead's product **Biktarvy**® (bictegravir 50mg / emtricitabine 200mg / tenofovir alafenamide 25mg) after discovering that the bottles contained foreign tablets and no Biktarvy tablets. Additionally, a fifth incident was reported in which a bottle of **Descovy**® (emtricitabine 200mg / tenofovir alafenamide 25mg) contained foreign tablets and no Descovy tablets.

The pharmacies reported purchasing the suspect Biktarvy and Descovy bottles from Safe Chain Solutions, LLC, a wholesaler located in Cambridge, Maryland (Safe Chain). Safe Chain has informed us that it purchased Biktarvy from Gentek LLC. Neither Safe Chain nor Gentek is an authorized distributor of Gilead products, including Biktarvy and Descovy. Gilead has

identified false information on Safe Chain's Drug Supply Chain Security Act Documentation (pedigree documentation) provided to pharmacies with their purchase of Biktarvy. The investigation is continuing; however, we have not found any evidence suggesting that the integrity of these bottles was compromised at Gilead or our contractors.

Gilead is working closely with the U.S. Food and Drug Administration (FDA) to prevent further distribution of illegitimate drug products, including Biktarvy and Descovy, and to support the Agency's investigation into the reported instances. **Gilead recommends that you purchase Gilead products directly from Gilead authorized distributors as our authorized distributors share our commitment to patient safety.** A list of Gilead's authorized distributors of record is available on our corporate website at: <https://www.gilead.com/purpose/medication-access/authorized-distributors>.

Based on a visual inspection of the four Biktarvy bottles and the one Descovy bottle, Gilead has determined that the Biktarvy bottles did not contain Biktarvy tablets and the Descovy bottle did not contain Descovy tablets. For three of the four Biktarvy bottles the induction seals were tampered with and the Descovy bottle is not consistent with genuine Descovy packaging. Further assessments are underway.

If you identify any potentially suspect Gilead product, please immediately contact Gilead Product Quality Complaints toll free at [1-800-445-3235](tel:1-800-445-3235) (select option 2) or email qualitycomplaints@gilead.com. We will assist you in verifying the product and the legitimacy of the supply chain as asserted on the Drug Supply Chain Security Act Documentation that accompanied the transaction for each product.

Please report all adverse events, following or coincident with the use of any Gilead product to Gilead Sciences Global Patient Safety at [1-800-445-3235](tel:1-800-445-3235), (select option 3), or to the FDA MedWatch Program by phone ([1-800-FDA-1088](tel:1-800-FDA-1088)), by fax ([1-800-FDA-0178](tel:1-800-FDA-0178)) or via the internet www.fda.gov/medwatch/report.htm.

To view the Biktarvy Prescribing Information, please click [here](#).
To view the Descovy Prescribing Information, please click [here](#).

Sincerely,

David Piontkowsky, JD, MD
Vice President, Medical Affairs, Gilead Sciences, Inc.

Gilead Sciences, Inc. [333 Lakeside Drive Foster City, CA 94404 USA](https://www.gilead.com)
phone 650 574 3000 facsimile 650 578 9264

www.gilead.com

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Worldwide Pharma Sales Group Inc.

455 NE Fifth Avenue Suite D434

Delray Beach, Florida 33483

215.595.3932

adam@pharmasales.com



**SafeChain
Solutions**

Dear Valued Customer:

Safe Chain is writing to address an email recently sent from Gilead Sciences. Safe Chain follows all laws and compliance protocols required by the Drug Supply Chain Security Act. Gilead's email implies a small amount of Gilead products sold by Safe Chain were somehow compromised somewhere along the supply chain prior to being received by the patient. The two Gilead products referenced are Biktarvy and Descovy.

Here are the facts as it pertains to Safe Chain Solutions, these transactions and these products:

Safe Chain was made aware of this situation, it reported this to Gilead immediately. Safe Chain sought to assist and cooperate with Gilead as needed. To our knowledge, Gilead never issued a product recall, nor have we been informed that Gilead notified the Food and Drug Administration as required.

Safe Chain instantly requested advice of counsel on how to best safeguard our clients and their patients, then further rectify the situation.

Safe Chain immediately flagged the associated product lot numbers and quarantined any remaining product that had the same NDC and lot numbers. Safe Chain also refused any future units reflecting said lot numbers.

The product in question was purchased from a licensed wholesaler (Gentek LLC) and the T3 documents were traced back to a Gilead Authorized Distributor.

Safe Chain currently distributes thousands of products purchased from dozens of pharmaceutical manufacturers and licensed wholesalers. The products in question, and all products that are distributed by Safe Chain, have proper T3 documentation tracing the products back to the manufacturer or their Authorized Distributor.

These problems referenced by Gilead specifically point to products purchased from one licensed wholesaler, Gentek LLC.

As of late 2020, Safe Chain no longer sources any products from Gentek LLC and has had no other similar issues since then.

Safe Chain only sells finished goods as a Wholesale Distributor and is not a repacker. Safe Chain never opens or tampers with any packaging or products.

Safe Chain works with thousands of customers and tens of thousands of products each year and has never had a claim as such. Safe Chain has procedures in place to ensure the integrity of all products we sell and distribute. For questions about this letter or any of our products, please contact our Compliance Department at Compliance@SafeChain.com.

Sincerely,

The Safe Chain Team